Insight

March-In Rights: A Hostile Regulatory Environment

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Executive Summary

- As part of its initiative on march-in rights – the practice of relicensing patents that received federal funding – to make products more affordable to the public, the Biden Administration released an interagency draft framework under the Bayh-Dole Act to permit the government to march-in for medical products and prescription drugs.
- In particular, the draft framework would allow an appropriate federal agency to march-in for medical products and prescription drugs if their prices are "too high" or their production is "too slow."
- This insight reviews two proposed march-in health care scenarios presented in the proposed interagency draft framework to better understand the long-term negative impact march-in rights would have on innovation as well as patient access to the newest medicines.

Introduction

As part of its initiative on march-in rights – the practice of relicensing patents that received federal funding – to make products more affordable to the public, the Biden Administration released an interagency draft framework under the Bayh-Dole Act[i] to permit the government to march-in for medical products and prescription drugs. In terms of medical products and prescription drugs, this initiative diverges from the Biden Administration's previous position which rejected earlier petitions to use march-in rights.

Under this framework, march-in rights used for medical products and prescription drugs could be deployed f the price is "too high" or production is "too slow." Under current law, if taxpayer dollars funded an invention, the appropriate federal agency can march-in to a

private company and relicense that product to another business regardless of industry sector. Furthermore, the Biden Administration stated that price, for the first time, can be a factor in an agency determining if a product is not accessible to the public. The National Institute of Standards and Technology published the interagency framework and comments are due by February 6, 2024.

This insight reviews two proposed march-in health care scenarios presented in the proposed interagency draft framework to better understand the long-term negative impact march-in rights would have on innovation as well as patient access to the newest medicines.

Background: The Bayh-Dole Act and Prescription Drugs

The Bayh-Dole Act, passed in 1980, permits the appropriate federal agency under specific circumstances to grant itself a license (patent) for innovations that received federal research funding.[ii] A private company or contractor may hold a patent from a university, nonprofit research institution, or small business that was derived even in part from federal funding. As of 2023, no agency has ever exercised march-in rights. Most recently, in March 2023, the Department of Health and Human Services (HHS) via the National Institutes of Health (NIH) rejected a petition on the use of march-in rights to lower the cost of Xtandi (enzalutamide), a prostate cancer drug. The NIH found that Xtandi was widely available to the public on the market. In 2004, under the Bush Administration, the NIH denied a march-in petition for Xalatan, a glaucoma treatment. In 2013, under the Obama Administration, the NIH denied a march-in petition on Norvir, an HIV/AIDS drug.

Concern around the cost of prescription drugs has persisted over the past 20 years. In 2002, prior to the passage of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 that created Medicare Part D, *The Washington Post* published an op-ed arguing for the use of march-in rights to reduce prescription drug costs. The authors argued that "As of 1997, 54 of 84 anti-cancer drugs approved by the Food and Drug Administration were the products of federal funding." Indeed, the federal government remains the largest funder of basic research that identifies new disease mechanisms spending over $700 billion from 1995 to 2020, according to the Congressional Budget Office (CBO). These federal monies, according to CBO and other empirical studies, have increased private research and development. For example, one study found that "in the decade following an increase in NIH funding, private [research and development] spending grew by about eight times as much as the increase in that funding." The difference in spending can be summarized as federal monies supporting basic research to discover new drugs whereas private monies are used largely for clinical testing, safety, and other requirements to bring a product to market. Notably, the late Senators Birch Bayh (D-IN) and Bob Dole (R-KS) responded directly to the 2002 op-ed stating that the intent of the law was to "entice the private sector to seek public-

private research collaboration rather than focusing on its own proprietary research." In other words, the intent of the law was to encourage the private pharmaceutical sector to engage with federally funded academic research to develop new and innovative products for the American public.

The partnership between federal and private funding is essential to bring new drugs to market. As the Association of American Universities and others expressed in a recent letter to HHS Secretary Xaiver Becerra, exercising march-in rights could reduce private investment and thus prevent new lifesaving research and medicines from reaching patients. Moreover, the coalition highlights that prior to 1980, the government licensed about "5 [percent] of its 30,000 patents to firms looking to perform additional research and development to commercialize the discoveries." Without private investment, public research would not have developed into significant discoveries or innovations.

Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights

The draft guidance included eight example scenarios across various industries where march-in rights could be justified. This section discusses the prescription drug examples further.

Scenario One: *A biotech company has partnered with a U.S. government-funded university to develop treatments for autoimmune skin diseases. The company was granted an exclusive license to a government funded patent owned by the university. The patent claims a new compound that has shown promise in pre-clinical trials for psoriasis. The company has also separately developed another psoriasis treatment and that second treatment—which recently received [Food and Drug Administration] FDA approval—was developed solely by the company without any government support. Once the company secured FDA approval for that second treatment, it appears to have stopped all work on the patented compound that was invented by the government-funded university. A second company has approached both parties for a license to the university-owned patent, but its request was denied, so the second company has asked the government funding agency to march-in and require the university to grant it a license to the university patent.*

Discussion: First, as almost all basic science is funded by the federal government, it is unlikely that a pharmaceutical company would create a second patent without any information learned from similar sources. In fact, a 2023 study found that the NIH funding contributed to 99.4 percent of drugs approved from 2010 to 2019. Second, it is less likely that the company would bring the first patent to pre-clinical trial and then subsequently abandon it if the second product had already passed through the clinical trial process and

was about to receive FDA approval. A recent study highlighted that "New drug and device approval in the United States take an average of 12 and 7 years, respectively, from pre-clinical testing to approval." Third, it seems unlikely that another company would want to take on a product simply because it showed some pre-clinical trial promise.

Conclusion: This scenario appears to assume that pharmaceutical companies purchase patents and then shelve them if another product receives FDA approval. A company could stop investing in a product for a variety of reasons – none of them related to the patent's original source of funding. Finally, it is increasingly unlikely that an FDA approved drug was created without any federal monies, as almost all U.S. drug development stems from federal investment in basic research.

Scenario Two: *A government-funded university, after years of both broad and targeted marketing efforts, executed an exclusive license for a new compound demonstrated effective in Phase III clinical trials for treating Alzheimer's disease with a large Swiss pharmaceutical company active in drug development and the manufacture of proprietary medicines. The new compound was government-funded in its initial stages of development. The terms of the exclusive license did not reference the Bayh-Dole regulations and requirement for U.S. manufacturing unless waived by the government. The exclusive licensee has begun manufacturing limited quantities of the active pharmaceutical ingredient (API) of the compound at its existing facilities in Switzerland prior to FDA approval. The Swiss company has no manufacturing facilities in the U.S. The government-funded university self-reported to the funding agency the deficiency in the terms of the exclusive license and reported the status of manufacturing the API. The government funded university has not requested a waiver. The head of the agency has asked about possible use of march-in rights.*

Discussion: First, a growing number of APIs are manufactured in India and China, a public health and security concern highlighted in a 2019 report by the U.S.-China Economic and Security and Review Commission. The United States Pharmacopeia noted that "The FDA analysis showed that 72 percent of API facilities supplying the U.S. market are overseas, with 13 percent in China." Second, why would the U.S. government not waive the domestic manufacturing requirement, as the FDA entered a Mutual Recognition Agreement (MRA) with Switzerland in 2023? For reference, the United States only holds three MRAs—Switzerland, United Kingdom, and European Union. Third, it seems to be a poor justification to relicense this product based on Phase 3 data as it only 25 to 30 percent of drugs move from a Phase 3 to a Phase 4 clinical trial.

Conclusion: The scenario described above assumes that a compound (without FDA approval) should be relicensed to a U.S.-based manufacturer based only on Phase 3 data. This theoretical product is not FDA approved nor can it be assumed it would receive

approval at this stage. Moreover, if the United States holds an MRA with Switzerland, making it a country in which the United States recognizes manufacturing practices, why would the government be less likely to waive the domestic manufacturing requirement? Using march-in rights in this scenario is more likely to delay a potentially effective compound from receiving FDA approval.

Conclusion

The two scenarios proposed in the interagency framework to justify the use of march-in rights do not appear to demonstrate that relicensing drug patents would reduce costs for patients or improve access to new medicines. Moreover, the use of march-in rights is likely to reduce private investment in public research, the foundation for the majority of new discoveries and innovative products. If the government relicenses patents, private companies may return to their own research – which conflicts with the intent of the Bayh-Dole Act to incentivize public-private collaboration.

The United States is a leader in medical innovation and prescription drug development. Finalizing a march-in framework and respective federal agency authority will just be another obstacle to pharmaceutical innovation in an increasingly hostile regulatory environment.

[i] The Bayh-Dole Act was officially titled The University and Small Business Patent Procedures Act of 1980

[ii] Please see Section §401.6 of 35 U.S.C. 206; DOO 30-2A for additional details.